



JUL 5 2005

Dear Manufacturer:

The Food and Drug Administration (FDA) has received several inquiries regarding the status of "and/or" ingredient labeling of nutritive sweeteners in soft drink products in light of the November 26, 2004 *Federal Register* (FR) Notice (69 FR 68831) withdrawing the proposed rule to permit "and/or" labeling for nutritive sweeteners in soft drinks.

In general, the ingredients of a multi-ingredient food must be declared on the food label by their common or usual names; FDA may grant exemptions to this requirement based on a finding that compliance is impracticable or will result in deception or unfair competition (21 U.S.C. 343(i)(2)). As you are probably aware, FDA received a petition in 1984 from the National Soft Drink Association (NSDA) requesting "and/or" labeling for sweeteners in soft drinks. This was one of several petitions pending with the Agency that addressed alternate ways to declare sweeteners in foods. In the *Federal Register* of June 21, 1991 (56 FR 28592 at 28605-07), FDA discussed the sweetener labeling issues raised in these petitions. The Agency denied the NSDA petition, concluding that "and/or" labeling for sweeteners was not warranted because the petitions and other available evidence did not show that requiring declaration of specific sweeteners in soft drinks was impracticable or would result in deception or unfair competition.

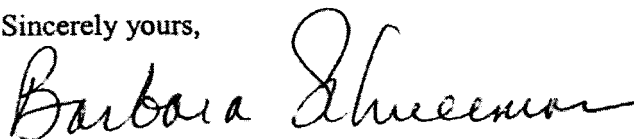
The NSDA submitted a comment requesting the Agency to reconsider its denial of the petition. The NSDA's comment maintained that the soft drink industry's practice of using different sweetener formulations for the same product depending on supply and time of year, in conjunction with considerations like meeting consumer demands during peak selling periods, obtaining product labels from national suppliers, and the huge sales volume of the bottler system, necessitated the flexibility of an "and/or" labeling system. FDA reconsidered its denial and in the *Federal Register* of January 6, 1993 (58 FR 2950), published a proposed rule to permit "and/or" labeling for nutritive sweeteners in soft drinks, if the manufacturer was unable to adhere to a constant pattern of nutritive sweeteners in soft drinks. In the preamble to this proposed rule (58 FR at 2953-54), the Agency stated that it wished to make clear that its final decision would be based largely on the comments that it received to justify adoption of the proposal. The preamble also stated that industry would have to produce data to demonstrate that it is in fact impracticable to produce the very limited number of versions of a label that would be necessary if an exemption were not granted. Finally, the preamble stated that those who opposed granting the exemption would have to come forward with strong reasons why the requested exemption should not be granted in the face of data from industry establishing significant costs from strict compliance.

In a May 28, 1997 letter, the Office of Food Labeling (the predecessor to the Office of Nutritional Products, Labeling and Dietary Supplements) advised the NSDA that FDA was not initiating enforcement actions against soft drink manufacturers that used "and/or" labeling for nutritive sweeteners in soft drinks and would likely continue to exercise enforcement discretion until rulemaking on this issue was complete.

In the *Federal Register* of April 22, 2003 (68 FR 19766), as part of former Secretary Thompson's regulatory reform initiative, FDA announced its intent to withdraw a number of proposed rules that were no longer considered viable candidates for final action based on the Agency's limited resources and changing priorities. This notice included the proposed rule for "and/or" labeling for nutritive sweeteners in soft drinks. The proposed rule was withdrawn by notice published in the *Federal Register* of November 26, 2004 (69 FR 68831). In response to comments received to the April 2003 notice, FDA stated, in part, that the Agency had received no data demonstrating that declaring specific sweeteners in soft drinks was impracticable and therefore did not have a sufficient basis to proceed to a final rule allowing "and/or" labeling for soft drinks.

Withdrawal of the proposed rule completes the rulemaking on this issue. Consistent with FDA's May 28, 1997 letter, the Agency did not pursue any enforcement action against soft drink manufacturers who used "and/or" labeling while the rulemaking was pending. However, now that the proposal has been withdrawn, the situation addressed in the letter no longer applies. Accordingly, FDA encourages the soft drink industry to review the ingredient statements on their soft drink labels and assure that the sweetening ingredients in the product are listed accurately.

Sincerely yours,

A handwritten signature in black ink, reading "Barbara O. Schneeman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
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